



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299
7590 07/01/2005			EXAMINER	
EDGAR R. CATACTIONS			FUBARA, BLESSING M	
TRASKBRITT, PC			ART UNIT	
P.O. BOX 2550			PAPER NUMBER	
SALT LAKE CITY, UT 84110			1618	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/627,531	<b>Applicant(s)</b> BERRY ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-21,23-27,29-31,33-41 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-21,23-27,29-31,33-41 and 49-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/16/05, 2/11/05, 1/07/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114 filed 03/18/05; supplemental IDS filed 01/07/2005, 02/11/05 and 05/16/05, amendment and remarks filed 01/07/05. Claims 17-21, 23-27, 29-31, 33-41 and 49-53 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 03/18/05 has been entered.

#### ***Claim Rejections - 35 USC § 102***

2. The rejection of claims 17-19, 24-27, 29-31, 33, 36, 52 and 53 under 35 U.S.C. 102(b) as being anticipated by Daher et al. (US 4,376,118) is withdrawn because amended generic claims recite specific beneficial agents. Applicants' arguments with respect to the rejection under 35 USC 102 are thus not addressed.

#### ***Claim Rejections - 35 USC § 103***

3. Claims 17-21, 23-27, 29-31, 33-41 and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. US 4,376,118) in view of Bogdanský et al. (US 5,284,655).

Daher discloses a formulation that comprises tetracycline antibiotic, antioxidant, non-aqueous diluent, non-aqueous solvent, non-aqueous non-ionic solubilizer and non-aqueous anionic solubilizer (abstract). Lauryl lactate is a diluent (column 1, line 58), polysorbate,

Art Unit: 1618

ethylene oxide propylene oxide block copolymers are non-aqueous solubilizers (column 2, lines 6-12) and ethanol or methanol or N-methyl-pyrrolidone are solvents (column 2, lines 51-53).

Adapting the formulation for implantation is a future intended use/route of administering the composition and future intended use/route of administering carries no patentable weight in a composition claim. Regarding the amounts of the active agents as recited in claims 20 and 21, one of ordinary skill in the art is capable of incorporating amounts of the active agents that would be effective to elicit the desired effect in a subject in need thereof for the said medication. There is also no demonstration in applicants' specification showing that the amounts recited for the beneficial agents provide unusual and unexpected results. Regarding claims 40 and 41, it is within the purview of the ordinary or skilled artisan to determine duration of treatment for effective management of the condition being treated and tetracycline and tetracycline can be delivered by implantation (see teaching reference, Jernberg, US 5,290,271). The skilled artisan or the ordinary person in the art is able to determine how much solvent, surfactant and polymer to use.

Daher discloses tetracycline antibiotic formulation. Daher does not disclose the formulation to contain protein. However, Bogdansky discloses a composition that comprises autogenous or alogenic bone particles, polyvinyl pyrrolidone (polymer), glycerol monolaurate and tetracycline antibiotic or protein (column 4, line 47; column 5, lines 31, 32 and column 3, line 50 to column 6 line 11). Protein and tetracycline are equivalent as active agents in Bogdansky. The bone formulation in Bogdansky is designed to be applied directly to the site of the defect and it is stated in column 6, lines 33-41: "among the bone repair applications for which the use of the osteogenic composition of this invention is eminently suited are: standard or

Art Unit: 1618

custom arthroplasty prosthesis; reconstruction of skeletal or other osseous defects; enhancing or augmenting the effectiveness of internal and external fixation devices, bone plates, etc.; as a replacement of corticocancellous strips, and so forth.” Also, in column 2, line 67 to column 3 line 4, Bogdanský discloses that the bone formation containing the protein can be administered by injection, a parenteral administration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the tetracycline formulation of Daher. One having ordinary skill in the art would have been motivated to substitute protein for tetracycline with the expectation that the protein containing formulation would be flowable and suitable for implantation or injection.

***Response to Arguments***

Applicants' argument with respect to GB 1,049,104; Jernberg in US 5,290,271 and Bergy in US 3,632,768 is not addressed since those rejections are not further made in the current Office action.

4. Applicants' arguments with respect to combining Daher and Bogdanský and filed 03/18/05 have been fully considered but they are not persuasive.

Bogdanský is relied upon for a teaching of a composition that can comprise tetracycline and protein and thus one or the other or both can be used in the formulation.

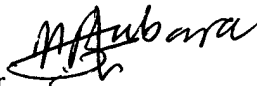
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name of the Patent Examiner.